K091873

SEP 1 8 2009

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

Submitter	SPINEART International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 799 40 25 Fax : +41 22 799 40 26 Mail : fpennesi@spineart.ch Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Preparation date	June 9, 2009
Trade Name	TRYPTIK ca
Classification Name	Intervertebral body fusion device- Cervical
Class	II
Product Code	ODP
CFR section	888.3080
Device panel	Orthopedic
Legally marketed predicate devices	AFFINITY ANTERIOR CERVICAL CAGE SYSTEM (P000028) manufactured by MEDTRONIC, BAK/C CERVICAL INTERBODY FUSION DEVICE (P980048) manufactured by ZIMMER SPINE, CRYSTAL (K073351) manufactured by SPINAL ELEMENTS, INC
Description	TRYPTIK ca of cervical interbody fusion devices made of PEEK OPTIMA conforming ASTM F2026. Markers made of titanium conforming ASTM F136 are used to visualize the position of the implant in the disc space. TRYPTIK ca devices are designed for an anterior approach. All devices are supplied sterile.

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Intended Use	TRYPTIK®ca cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. TRYPTIK®ca are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. TRYPTIK®ca are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage
Performance data	TRYPTIK ca cervical interbody fusion devices conform to Class II Special Controls Guidance Document: Intervertebral Body Fusion Device- Document issued on: June 12, 2007
Substantial equivalence	TRYPTIK cervical interbody fusion device is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

Spineart
% Franck Pennesi
International Center
Cointrin 20 Route de Pre-Bois, CP1813
Geneva
Switzerland 1215

Re: K091873
Trade/Device Name: TRYPTIK CA Anterior Intersomatic Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: June 22, 2009
Received: June 23, 2009

Dear Mr. Pennesi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

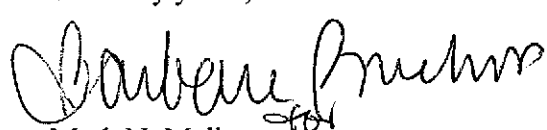
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K091873

Device Name: TRYPTIK ca

Indications for Use:

TRYPTIK®ca cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. TRYPTIK®ca are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. TRYPTIK®ca are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kareem S. Bursey for MxM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091873